UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: ***Barbara & Gary Smith v Ethicon, Inc., et al*** ***Case No. 2:12cv04791***	

EXPERT REPORT OF DOUGLAS H. GRIER, M.D.

Review and opinion in the case of Barbara Smith, DOB 3/23/41

Barbara Smith was born on March 23, 1941. At the time of her April 17, 2006, implant with Dr. Peter Zenthoefer, she was 65 years old and smoked approximately 10 cigarettes per day. Mrs. Smith is a gravida 3 para 3 married female with 3 vaginal births with episiotomies and one delivery which required the use of forceps. She has been a smoker since the 1950s. Her relevant surgical history includes an ovarian cyst removal in 1975 and a bladder repair and total abdominal hysterectomy in 1981. According to Mrs. Smith, she suffered from severe adhesive disease, which her surgeon encountered during her hysterectomy. She has a history of obesity, depression, irritable bowel syndrome, fibromyalgia, hypertension, and anxiety.

Plaintiff's medical history includes the following:

In October of 1999, Mrs. Smith underwent colonoscopy which determined she had diverticular disease. [SMITHB_PSR_660] She was diagnosed with fibromyalgia around 2001. [SMITHB_PSR_00001-2] Mrs. Smith's records indicate that she was prescribed Zoloft, Estrace, Zestril, Levsinex, Lipitor, and Claritin D in October 2002. During 2003, Mrs. Smith was having problems with her antidepressant not working for her, and she reported increased anxiety and depression. At a May 14, 2003, psychological visit, Mrs. Smith reported that she had to quit her adult learning program due to multiple episodes of bowel incontinence, which she described as "blowouts," spanning about six months before the visit. [SMITHB_PSR_00014-16] The following day, she was diagnosed with irritable bowel syndrome and fibromyalgia. [SMITHB_PSR_00019-20] By July of 2003, Mrs. Smith was having diarrhea three to four times daily, two or three times per week. [SMITHB_PSR_00022-23] Dr. Michelle Ritter noted she had rectal laxity.

Dr. Ritter referred Mrs. Smith to Dr. Jeremy Lake, a gastroenterologist, who in August of 2003, noted she had soiling of her clothing three days per week due to anal incontinence. Mrs. Smith described urgency to defecate to Dr. Lake. Dr. Lake noted that her diminished rectal tone was possibly related to her vaginal births. [SMITHB_PSR_00027-28] On October 11, 2003, Mrs. Smith reported that the scar tissue from her hysterectomy was bothering her, making it so she could not get comfortable when at rest or when walking due to the pain. [SMITHB_PSR_00042] Mrs. Smith then went into urgent care complaining of burning pain in her LLQ; she related this pain to her TAH in 1981, stating that she has had intermittent pain since that time. [SMITHB_PSR_00043] An August 2005 visit noted that Mrs. Smith was on postmenopausal HRT. [SMITHB_PSR_120]

On December 9, 2005, Mrs. Smith presented with 3 days of dysuria; Dr. Ritter noted a cystocele finding on examination. [SMITHB_PSR_00132] Three days later, she complained of urgency and frequency. [SMITHB_PSR_00133] Pm December 12, 2005, Mrs. Smith saw Dr. Peter Miksovsky for pelvic pain and pressure, where she reported a need to lean to one side in order to void; she described urge incontinence upon awakening daily. Dr. Miksovsky found a 1-2 degree cystocele, 1st degree rectocele, and 1st degree vaginal cuff descent. His impression was symptomatic pelvic floor relaxation, urge incontinence, and pelvic fullness. [SMITHB_PSR_00136-138] She discussed options including surgery and pessary use; indicating

that she preferred surgery but would try a pessary pending an urogyn appointment. Thus, she was fitted with a number 4 ring pessary and given a referral for urodynamics and surgery planning. Just one day following use of the pessary, Mrs. Smith told the nurse that she stopped wearing it due to rectal discomfort and reiterated her preference for surgical treatment. [SMITHB_PSR_00138] She was fitted with a new pessary, but the new size still caused her discomfort and bleeding.

Mrs. Smith was referred to implanting surgeon Dr. Peter Zenthoefer, whom she saw on January 30, 2006, with complaints that her insides were "falling out." She reported years of SUI, requiring daily mini-pads, urgency for a year, nocturia, and prolapse pressure. Mrs. Smith told Dr. Zenthoefer that she needed to always splint in order to have a bowel movement. Dr. Zenthoefer found the perineal body was attenuated and attributed this to a vaginal birth that required the use of forceps. Dr. Zenthoefer noted a large cystocele and a moderate large rectocele. [SMITHB_PSR_00145-147] He instructed her about Kegel exercises and diet modification. Two months later, Mrs. Smith told Dr. Zenthoefer's nurse practitioner that she did not want to continue with conservative treatment and desired surgery. [SMITHB_PSR_00152] Dr. Zenthoefer determined that Mrs. Smith was not an appropriate candidate for prolapse surgery with an abdominal approach due to her history of severe adhesive disease. Dr. Zenthoefer performed a pre-operative assessment on April 12, 2006; the plan was an A&P with Prolift and a trans-obturator tape procedure. [SMITHB_PSR_00155-157]

On April 17, 2006, Dr. Zenthoefer performed an A&P repair with Prolift and a TVT-O mid-urethral sling implant. He noted problems with hormones, anxiety, cystocele, rectocele, and ½ ppd smoking habit. [SMITHB_PSR_00744-746] The patient underwent an uneventful Anterior and Posterior Prolift with transobturator midurethral sling. The only aberration described was the use of a catheter guide to evert the urethra during needle passage.

Following surgery, Mrs. Smith had some right leg pain, but it resolved less than 10 days post-op. [SMITHB_PSR_00163] Six weeks post-op, Mrs. Smith reported being "very pleased" with her results, including no longer needing to splint for a bowel movement, no SUI, and no urgency; she did have some dysuria and cloudy urine. On May 31st, 2006, Dr. Zenthoefer noted a small blue stitch at the vaginal apex, and prescribed Premarin vaginal cream. [SMITHB_PSR_00165-166] Mrs. Smith did not follow up for a UTI U/A after this visit, and returned for treatment in August of 2006, when she was prescribed Macrobid. [SMITHB_PSR_00175] On August 23, 2006, Mrs. Smith reiterated that she was "very pleased" with her surgical results but was having problems with recurrent UTI and vaginal atrophy. Dr. Zenthoefer noted that she had discontinued her HRT one year prior due to hot flashes; he told her to continue with the vaginal estrogen and to stop smoking. [SMITHB_PSR_00177-178] He also noted that she was not sexually active due to her husband's impotence. Mrs. Smith appears to have had two UTIs in October and December of 2006.

At her one year surgical follow-up visit on July 12, 2007, Mrs. Smith reported to Dr. Zenthoefer that she was dry during the day but suffered from some urinary incontinence at night, coupled with nocturia, three times per night, and frequent UTIs, along with some recent bleeding. She

told him that the surgery had helped her 90%. Dr. Zenthoefer noted marked genital atrophy. [SMITHB_PSR_00198-199] To investigate her urethral bleeding, Dr. Zenthoefer performed a cystoscopy on August 2, 2007, which showed no mesh anywhere inside the bladder and was unremarkable. [SMITHB_PSR_00204]

Two years after her mesh surgeries, in April 2008, Mrs. Smith complained of her fibromyalgia pain being "out of control," "constant" and "daily." [SMITHB_PSR_00211-214] She had UTI type symptoms in April 2008 and again in February 2009. In May of 2010, Mrs. Smith presented with LLQ pain which she connected with scar tissue from her hysterectomy, along with one-monthly leg pain. [SMITHB_PSR_00277-281] In July of 2010, Mrs. Smith reported symptoms of UTI, but the cultures did not bear that out. She was diagnosed with atrophic vaginitis and given estrogen cream in November of 2010. [SMITHB_PSR_00308]

On January 7, 2011, Mrs. Smith was admitted to the hospital following a positive urinalysis that caused weakness, confusion, and poor ambulation. [SMITHB_PSR_00331-332] On January 12, she reported to Dr. Ritter that she was having symptoms like those before her mesh surgeries. Mrs. Smith returned to Dr. Zenthoefer on January 20, 2011, with complaints of OAB (three to four times per night, with one leaking episode) and UTI symptoms. He prescribed Premarin cream and scheduled a cystoscopy to evaluate possible mesh erosion. [SMITHB_PSR_00359-261]. He noted that Mrs. Smith was not using the vaginal estrogen cream properly and emphasized the importance using the cream as directed. [SMITHB_PSR_00259-261]

The cystourethroscopy Dr. Zenthoefer performed on January 25, 2011, showed no mesh erosions or lesions. [SMITHB_PSR_00365-366] On April 5, 2011, Dr. Zenthoefer noted Mrs. Smith was not sexually active, did not have SUI, and did not have prolapse symptoms. She did have vaginal atrophy. Dr. Zenthoefer noted about a 1 cm area of mesh erosion at Mrs. Smith's apex. He recommended to continue with Premarin cream and, if necessary, consider surgery in 3 months' time. [SMITHB_PSR_00388-392] By June, the exposure had not subsided, so surgery was scheduled to remove the mesh. [SMITHB_PSR_00401-403]

On July 14, 2011, Dr. Zenthoefer excised a 2.2 x 1.5 x 0.7 cm piece of mesh and tissue and performed a cystoscopy. [SMITHB_PSR_00583-586] Mrs. Smith had some retention after surgery and went home with a Foley catheter. At her post-operative appointment, Dr. Zenthoefer prescribed vaginal estrogen cream. [SMITHB_PSR_00438-440] On November 1, 2011, Mrs. Smith returned to Dr. Zenthoefer complaining of dysuria and frequency; his impression was UTI, atrophic vaginitis, and vaginal mesh exposure. [SMITHB_PSR_00446-448]

Mrs. Smith indicated that she had an additional excision surgery on August 16, 2012, but no records from any such procedure have been obtained.

The patient claims that she has suffered the following injuries as a result of her Prolift and TVT-O implants: pelvic pain, erosions, recurrent urinary problems, diarrhea, and infections. After performing an examination on January 7, 2017, Plaintiff's expert witness, Dr. Daniel Elliott, has offered the opinion that she has "pelvic pain consistent with pelvic floor myalgia that has been unchanged by the implantation of the Prolift meshes." Dr. Elliott opined that Plaintiff's

prognosis is poor for her pelvic pain and her overactive bladder, even with aggressive physical therapy, surgery, and biofeedback. Finally, he opined that Mrs. Smith was not able to give informed consent, that Dr. Zenthoefer was not able to obtain informed consent due to Ethicon's actions, that Mrs. Smith developed the complication of mesh exposure because of the implant, and that her medical bills were reasonable and necessary.

Independent Medical Examination Findings and Assessment:

Mrs. Smith presented to my office for examination on February 1, 2017. When I asked about her history during the IME, Mrs. Smith revealed that she is under a great deal of stress as she has just placed her husband in an assisted care facility due to his inability to walk or take care of his activities of daily living. Due to the patient's chronic back pain and fibromyalgia, it has been very difficult for her to take care of herself while assisting her husband. The patient has neglected her medical care and feels like she has had a bladder infection for many months. The patient receives her care from the Kaiser system and has not presented for evaluation or treatment in many months. The patient has significant incontinence both daytime and at night with nocturnal enuresis wearing 3 under pads per day. Her nocturia is every 2 hours with small volumes and voids often during the day. She is unable to control her bladder when standing and takes four oxycodone daily, continuing to smoke one half pack per day of cigarettes. I questioned the patient as to why she didn't seek care for her irritative voiding symptoms and she responded that in Kaiser she is not able to see more than a mid-level provider on her visits and has not been evaluated by an urologist or gynecologist in years. The patient's urine sample is grossly infected. The patient has chronic suprapubic pain which is worse when delaying voiding and is consistent with chronic cystitis that is manifested by her urinalysis on the day of examination.

B/P: 154/71, P: 78, T: 98.1, 5'1", 173 lbs.

Urinalysis: yellow/hazy, Ph 6, 3+ Leukocytes, 2+ protein, 2+heme, micro 30-50 WBC's, 10-2-RBC's, positive bacteria

Physical examination reveals a well-nourished and well-developed white female in no acute distress that is pleasant and cooperative. Abdomen- nondistended with suprapubic Pfannenstiel incision site well-healed and with suprapubic tenderness to deep palpation. Pelvic examination: Normal female introitus with no adductor longus or obturator tenderness to deep palpation. Palpation of the areas of Prolift arm placement is nontender and the patient has no pain with abduction or adduction of the thighs. The vaginal introitus is nontender and has normal appearance. Vaginal epithelium is mildly atrophic without any visible lesions or masses. Valsalva straining reveals a grade 1-2 anterior wall descent in the distal bladder neck area and no rectocele with excellent apex support. Digital palpation of the vagina revealed no tenderness posterior or laterally, no levator tenderness and no tenderness along the Prolift arms. Direct tenderness was noted anteriorly right greater than left along the floor of the bladder and trigone. No mesh exposure is noted throughout the vagina under direct vision or by palpation. Valsalva straining revealed slight urethral hypermobility but no leakage with the bladder half full. The patient's post void residual was found to be 63 mL by transabdominal

ultrasound. One area of the vagina was tender to direct deep palpation which corresponds to the bladder neck and toward the obturator membrane on the right.

Opinions

I do not think that Mrs. Smith's recurrent urinary problems, pelvic pain, erosion, and infections are attributable to any alleged defects in the Prolift Total or TVT-O implants.[1] The devices are safe and effective and have a positive benefit-to-risk profile. The mesh surgeries she had were more effective in treating prolapse and incontinence than alternative treatments would have been. The development and utilization of synthetic meshes for repair of vaginal prolapse over the past 25 years occurred because native tissue repairs have an unacceptably high failure rate. All stress incontinence and prolapse surgeries carry a risk of scarring, adhesion formation, infection, exposure or erosion, pain, pelvic pain, dyspareunia, bowel or bladder dysfunction, and failure of the operation. Her course is not indicative of a defect in the Prolift or the TVT-O.

Recurrent Urinary Problems

The patient manifested mixed urinary incontinence for years preoperatively and the TVT-O is not indicated or expected to treat urgency/frequency, bladder detrusor overactivity, or to prevent recurrent urinary tract infections. The fact that Mrs. Smith has persistent voiding dysfunction is unrelated to her previous TVT-O and Prolift surgery. Mrs. Smith has overactive bladder symptoms of urgency, frequency, and urge incontinence which also can be managed with overactive bladder medications. The patient states that she has never been offered evaluation or treatment of these symptoms by her healthcare providers at Kaiser Medical.

Pelvic Pain

The patient has multiple factors contributing to her chronic pelvic pain. The patient had previous pelvic surgery including hysterectomy and obstetrical scarring with an ongoing history of tobacco usage. She also has irritable bowel syndrome and chronic fibromyalgia which commonly causes pain flairs after surgical procedures and is exacerbated by stress. The most likely cause of her acute suprapubic and pelvic pain is active chronic cystitis, which has not been treated and the patient has not been provided chronic antibiotic urinary suppression to sterilize her urine and allow the bladder mucosa to heal over time. There is an area of point tenderness in the anterior vagina on the right which could be treated with trigger point injections using anesthetic/steroid solutions. The patient would also benefit from pelvic physical therapy and neuromodulation with medications such as gabapentin.

[1] In his report, Plaintiff's expert, Dr. Elliott, does not appear to attribute any alleged injuries to the TVT-O; if that is indeed the case, I agree with him. If he does attribute fault to the TVT-O, I reserve the right to amend my report to address those concerns.

Exposure

As with any surgery, potential complications exist that stem from the fact that, for reasons completely unrelated to the medical device used, human bodies may heal or respond differently than predicted. Wound complications can occur with any surgery, including other prolapse and incontinence repairs, and stem from a variety of factors, including local factors that directly impact the wound itself, and systemic factors relating to a particular individual. I believe that Mrs. Smith's issues stem from a wound healing problem that was complicated by her prior surgical procedures, including a seven-hour-long hysterectomy due to severe adhesive disease, and other conditions, including vaginal atrophy for which she non compliantly did not use prescribed estrogen therapy, obstetric scarring, obesity, hyperlipidemia, and ongoing history of smoking. Mrs. Smith is part of a small subset of women with tissue that has a propensity to scar. It has been reported that 3-8% of women require repeat surgery for mesh exposure following transvaginal mesh prolapse repair.[2]

Infections

Urinary tract infections "are considered to be the most common bacterial infection," accounting for nearly 7,000,000 office visits and 1,000,00 emergency room visits per year according to the 1997 National Ambulatory Medical Care Survey and National Hospital Ambulatory Medical Care Survey.[3] The female anatomy makes women prone to getting UTIs because the urethra is shorter in a woman than in a man, making it easier for bacteria to reach the bladder. According to the AUA, it "is estimated that 150 million UTIs occur yearly world-wide, accounting for $6 billion in health care expenditures. (AUA Medical Student Curriculum – Adult UTI, available at https://www.auanet.org/education/adult-uti.cfm.) As is the case for Mrs. Smith, when acute bladder infections are not treated and allowed to persist over weeks, months, and perhaps in her case over years, bacteria become incorporated within the epithelial lining of the bladder creating chronic cystitis, and chronic irritative voiding symptoms with the possibility of systemic infections including pyelonephritis. Indeed, Mrs. Smith developed a urinary tract infection 6 years ago that caused syncope and hospitalization. The patient currently suffers from acute and chronic cystitis with an active infection at the time of her examination that has gone untreated for many months and contributing to most of her current symptoms. The patient's symptoms are not caused by the Prolift mesh but rather due to chronic bladder infection which will take months to resolve. The patient is in desperate need of urological evaluation with urodynamics, cystoscopy, antibiotics, and anticholinergic medications. The patient also would benefit from pelvic physical therapy and possible trigger point injections along with nerve stabilizing medications such as gabapentin.

[2] Schimpf MO, et al., Graft and Mesh Use in Transvaginal Prolapse Repair: A Systematic Review. Obstet Gynecol. 2016 Jul;128(1):81-91; Maher C, et al., Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. Cochrane Database Syst Rev. 2016 Feb 9;2:CD012079.
[3] Foxman B, Epidemiology of Urinary Tract Infections: Incidence, Morbidity, and Economic Costs, Am J Med 2002 Jul 8;113 Suppl 1A:5S-13S.

I hereby incorporate by reference my general reports regarding the Prolift and TVT-O products submitted in this litigation.

The opinions set forth in this report are based on my review of medical records, depositions, medical literature, my examination of the plaintiff, and my education, training, and experience. I hold the opinions set forth in this report to a reasonable degree of medical certainty, and I reserve the right to amend or supplement this report if new information becomes available.

Date: 2/13/17

Douglas H. Grier, M.D.